In the United States Court of Federal Claims

No. 15-1273V
Originally Filed: May 18, 2022[*]
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NOT FOR PUBLICATION

HELENE QUINTANA,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Ronald C. Homer & Joseph Pepper, Conway Homer, P.C., Boston, MA, for the petitioner.

Joseph A. Lewis, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, for the respondent.

MEMORANDUM OPINION AND ORDER

***HERTLING*, Judge**

The petitioner, Helene Quintana, seeks review of a special master's decision denying her claim under the National Vaccine Injury Compensation Program ("Vaccine Program"). The petitioner alleges that an influenza ("flu") vaccine caused her uveitis, herpes keratitis, and related sequelae.[1] The special master found that the petitioner is not entitled to compensation.

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[*] Pursuant to Vaccine Rule 18(b), each party had 14 days after the filing of this opinion to notify the Court of any information that should be redacted from the decision for reasons of privilege or confidentiality. The Court did not receive any such notification. Accordingly, the Court publicly reissues the opinion in full.

[1] "Uveitis is 'an inflammation of part or all of the uvea, commonly involving the other tunics of the eye (sclera, cornea, and retina).' . . . The uvea is 'vascular layer of eyeball: the middle, pigmented, vascular coat of the eye, comprising the choroid, the ciliary body, and the iris[.]'" (ECF 92 at 1 n.4 (quoting *Dorland's Illustrated Medical Dictionary* 1990, 2014 (32d ed. 2012) ("*Dorland's*") (modification in original) (internal citations omitted).) "Herpes keratitis is 'a viral

The petitioner has moved for review of the special master's entitlement decision. She objects to the special master's limit on and weighing of the evidence and to the special master's application of the legal test for causation. The respondent, the Secretary of Health and Human Services, has opposed the petitioner's motion.

The special master's entitlement decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. The Court declines the petitioner's invitation to reweigh the evidence. Accordingly, the petitioner's motion for review is denied.

I. BACKGROUND[2]

A. Vaccination and Injury

On November 3, 2012, when the petitioner was a healthy 55-year-old, she received a flu vaccine. (ECF 92 at 4.) The petitioner visited Lilia Alvarez, D.O., on November 12. (*Id.*) The petitioner reported the onset of a stye after receiving the flu vaccine.[3] (*Id.*) Her eye had become red and swollen on November 5, and she had a fever on November 7 through November 8. (*Id.*) On November 10, she developed another stye, which became worse on November 11. (*Id.*) The doctor also noted that the petitioner was suffering from a cold. (*Id.*) Aside from the cold, the doctor assessed that the petitioner had bacterial conjunctivitis of the right eye greater than the left.[4] (*Id.*) During her return visits to Dr. Alvarez on November 13 and December 10, the petitioner reported improvements in her condition. (*Id.*) Dr. Alvarez diagnosed her condition as a bacterial infection. (*Id.*)

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infection of the eye caused by the herpes simplex virus ("HSV"). It is a virus of the genus *Simplexvirus* that is an etiologic agent of herpes simplex and causes predominantly non[-]genital infections. Primary infection usually occurs in early childhood and is often asymptomatic, although gingivostomatitis and pharyngitis may occur. The virus can pass along nerves and remain latent in ganglia, from which it may be reactivated. Called also herpes simplex virus ("HSV") . . . ." (*Id.* at 1-2 n.5 (quoting *Dorland's* at 979) (modifications in original).)

[2] The petitioner has not disputed the background facts and procedural history as set forth in the special master's entitlement decision (ECF 92). The Court relies on that decision in providing a summary of the relevant background for context only. The Court omits the special master's internal citations. For a full recitation of the facts, see the special master's public decision at *Quintana v. Sec'y of Health & Hum. Servs.*, No. 15-1273V, 2022 WL 621698 (Fed. Cl. Spec. Mstr. Feb. 15, 2022).

[3] "A stye or hordeolum is 'a localized, purulent, inflammatory staphylococcal infection of one or more sebaceous glands . . . of the eyelids[.]'" (ECF 92 at 4 n.7 (quoting *Dorland's* at 869, 1789) (modifications in original).)

[4] "Conjunctivitis is 'inflammation of the conjunctiva, generally consisting of conjunctival hyperemia associated with a discharge.'" (ECF 92 at 4 n.9 (quoting *Dorland's* at 405).)

On January 7, 2013, the petitioner visited ophthalmologist Michael W. Foote, M.D. The petitioner reported pain and redness in her right eye. (*Id.*) Upon examination, Dr. Foote evaluated that the petitioner's right eye had a marginal corneal ulcer, which he suspected was of an infectious etiology.[5] (*Id.* at 5.) On the petitioner's return visit to Dr. Foote the following day, a gram stain of the petitioner's discharge was negative for organism.[6] Dr. Foote considered the possibility that the petitioner's condition was peripheral ulcerative keratitis ("PUK") but suspected that its cause was more likely due to an infection.[7] (*Id.*) When the petitioner returned to Dr. Foote on January 11, he wrote that her condition was presumed to be infectious keratitis, but that he suspected it was PUK. (*Id.*)

On January 14, 2013, the petitioner returned to Dr. Foote. During this visit, Dr. Foote noted his suspicion that the petitioner had possible rheumatoid arthritis, as opposed to another autoimmune process, and he noted that the petitioner had a family history of autoimmune disorders. (*Id.*) He ordered several tests, the results of which showed a positive antinuclear antibody and HLA-B27 haplotype.[8] (*Id.*) On the day that the results were returned, January 28, Dr. Foote noted that the petitioner has a sister with possible rheumatoid arthritis and a son with possible ankylosing spondylitis, another autoimmune disorder.[9] (*Id.*) The petitioner's condition

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[5] "A corneal ulcer is also called ulcerative keratitis, which is 'keratitis with ulceration of the corneal epithelium[.]'" (ECF 92 at 5 n.11 (quoting *Dorland's* at 980) (modification in original).)

[6] A gram stain is a test that checks for the presence of bacteria. MedlinePlus Medical Encyclopedia, *Gram stain*, https://medlineplus.gov/ency/article/007621.htm (last visited May 9, 2022).

[7] PUK is "'a rare type of keratitis with inflammation of the limbal part of the cornea and nearby sclera, which have cellular infiltration, vascular changes, and ulceration that may cause blindness; it may be a complication of rheumatoid arthritis or a bacterial infection but sometimes is idiopathic.'" (ECF 92 at 1 n.3 (quoting *Dorland's* at 979).)

[8] "HLA-B27 is a blood test to look for a protein that is found on the surface of white blood cells. The protein is called human leukocyte antigen B27 (HLA-B27). Human leukocyte antigens (HLAs) are proteins that help the body's immune system tell the difference between its own cells and foreign, harmful substances. They are made from instructions by inherited genes." MedlinePlus Medical Encyclopedia, *HLA-B27 antigen*, https://medlineplus.gov/ency/article/003551.htm (last visited May 9, 2022). As the special master summarized, the respondent's expert "testified that a positive HLA-B27 haplotype, present in Petitioner, may result in a predisposition to a variety of autoimmune phenomenon, including uveitis." (ECF 92 at 44 n.85 (citing ECF 87, Tr. of Entitlement Hr'g at 85:1-3).)

[9] "Ankylosing spondylitis is 'a chronic multisystem inflammatory disorder associated with presence of the HLA-B27 antigen, and thus one of the group of seronegative spondyloarthropathies; it usually initially affects the sacroiliac joints and often later involves

had improved by March 2013, but her symptoms returned in May 2013. (*Id.* at 6.) In his notes reflecting follow-up visits by the petitioner, Dr. Foote referred to the petitioner's condition as PUK. (*Id.*)

On June 5, 2013, the petitioner visited rheumatologist Karen Smith, M.D., and internist Branch Craige, M.D. (*Id.*) Dr. Smith noted that the petitioner came to see her after experiencing severe ulcerative keratitis following her receipt of a flu vaccine. (*Id.*) Upon examination of the petitioner's ulcer in her right eye, Dr. Smith diagnosed the petitioner's condition as most likely Reiter's syndrome.[10] (*Id.*) Dr. Craige noted that the petitioner was frustrated over a second episode of PUK, which the petitioner attributed to allergies or the dry conditions in the Southwest, where she resides. (*Id.*) Almost a year and a half later, on December 1, 2014, the petitioner asked Dr. Craige to amend his initial notes to reflect the fact that the petitioner attributed her PUK to a flu vaccine. (*Id.*) Dr. Craige's assessments of the petitioner's ailment included Reiter's syndrome and positive HLA-B27. (*Id.* at 7.)

During June and July 2013, the petitioner visited Dr. Foote on two more occasions and Dr. Smith on three more occasions. (*Id.*) On July 17, Dr. Smith noted that the petitioner exhibited severe uveitis with hypopyon, and that the severity and suddenness of the petitioner's condition suggested Behcet's syndrome.[11] (*Id.*) On July 26, Dr. Smith diagnosed the petitioner's condition as hypopyon uveitis and noted that she would defer to ophthalmologists. (*Id.*)

On July 26, 2013, the petitioner visited two ophthalmologists, Mario Di Pascuale, M.D., and Ruben Ramirez, M.D. (*Id.* at 8.) Both doctors' notes reflect that the petitioner's condition occurred after a flu vaccine. (*Id.*) Dr. Di Pascuale diagnosed the petitioner's condition as PUK, and Dr. Ramirez diagnosed her condition as severe vasculitis with associated keratitis. (*Id.*) Dr.

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other joints of the axial skeleton and peripheral joints, causing pain and progressive stiffness and restricted range of motion. Extraskeletal manifestations include ocular, pulmonary, cardiovascular, renal, and neurologic complications.'" (ECF 92 at 5-6 n.16 (quoting *Dorland's* at 1754).)

[10] "Reiter's syndrome is 'the triad of acute aseptic arthritis, nongonococcal urethritis, and conjunctivitis; . . . It usually affects young men and runs a self-limited but relapsing course. Some authorities now consider this symptom complex to be more appropriately classified as reactive arthritis and not distinguished or named separately.'" (ECF 92 at 6 n.18 (quoting *Dorland's* at 1845) (modification in original).)

[11] "Hypopyon is 'an accumulation of pus in the anterior chamber of the eye.'" (ECF 92 at 7 n.23 (quoting *Dorland's* at 905).) "Behcet's syndrome is 'a variant of neutrophilic dermatosis of unknown etiology, involving the small blood vessels, characterized by recurrent aphthous ulceration of oral and pharyngeal mucous membranes and genitalia, with skin lesions, severe uveitis, retinal vasculitis, optic atrophy, and often involvement of the joints, gastrointestinal system, and central nervous system.'" (*Id.* at 7 n.26 (quoting *Dorland's* at 1822).)

Ramirez noted that it was unclear whether the condition was infectious because a culture was negative. (*Id.*)

While on a trip to Norway in August 2013, the petitioner's symptoms returned, and she was admitted to the eye department at Oslo University Hospital. (*Id.*) In a letter written to document the petitioner's condition, Atle Einar Østern, M.D., wrote that during her visit the petitioner's right eye had a corneal edema with a large corneal epithelial defect.[12] (*Id.*) Even though all specimen cultures were negative, Dr. Østern noted that the petitioner's condition might be consistent with an initial stromal or endothelial herpes keratitis. (*Id.*)

Upon returning to the United States in late August, the petitioner visited Dr. Smith, who noted the diagnosis from Norway and recorded that a biopsy of her eye had revealed positive antibodies in the serum. (*Id.*) Dr. Smith diagnosed the petitioner's condition as Reiter's keratitis with herpes as the aggravating driver. (*Id.*)

Throughout 2014, the petitioner continued to visit Drs. Di Pascuale, Foote, and Smith. (*Id.* at 8-12.) In April 2014, Dr. Foote noted that the severity of the ulcer was improving and that the condition had resolved. (*Id.* at 9.) He also noted that, although initially presented with PUK, the petitioner's condition was ultimately diagnosed as herpetic keratouveitis exacerbated by her HLA-B27 status.[13] (*Id.*) In the same month, Dr. Di Pascuale noted that the petitioner no longer had a corneal ulcer but had a corneal scar and neovascularization of the cornea. (*Id.*) In November 2014, Dr. Smith noted that the petitioner was generally stable but had a permanent eye injury. (*Id.* at 10.) Dr. Smith wrote that it was immunologically possible that the flu vaccine could have been the trigger. (*Id.*)

In May 2016, the petitioner reported to Dr. Smith that she had had an adverse reaction to a skin test for tuberculosis, even though she had previously received the Bacille Calmette-Guerin vaccine for tuberculosis. (*Id.* at 11.) Upon examination, Dr. Smith determined that the petitioner

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[12] "Corneal edema is defined as the increase in the thickness of cornea due to the accumulation of extracellular fluid in epithelium and stroma resulting in loss of corneal transparency." EyeWiki, *Corneal Edema*, https://eyewiki.aao.org/Corneal_Edema (last visited May 9, 2022). "Corneal epithelial defects are focal areas of epithelial (outermost corneal layer) loss . . . ." EyeWiki, *Corneal Epithelial Defect*, https://eyewiki.org/Corneal_Epithelial_Defect (last visited May 9, 2022).

[13] "Herpetic keratouveitis is '1. Keratitis caused by infection with herpes simplex virus, often with dendritic ulceration . . . 2. Keratitis occurring as a complication of herpes zoster ophthalmicus.'" (ECF 92 at 9 n.29 (quoting *Dorland's* at 979) (modifications in original).)

had erythema and redness in both eyes.[14] (*Id.*) Dr. Smith noted that the petitioner should avoid vaccines because they activate her eye disease. (*Id.*)

In late 2017, the petitioner returned to Dr. Østern in Norway. (*Id.* at 12.) Dr. Østern summarized the petitioner's medical history, noting that the petitioner's eye condition had developed after receiving the flu vaccine. (*Id.*) Dr. Østern wrote that her diagnosis was assumed to be residual herpes keratitis with a uveitis reaction in her right eye. (*Id.*) Noting the petitioner's reaction to the tuberculosis test in 2016, Dr. Østern wrote that the petitioner seems to react strongly, including around the eyes, to vaccines, which are assumed to set off her herpes keratitis secondarily. (*Id.*)

B. Petition for Compensation

On October 28, 2015, the petitioner filed her petition under the Vaccine Program seeking compensation for PUK, uveitis, herpes keratitis, and related sequelae alleged to have been caused by the November 2012 flu vaccine. (ECF 1.)

After the parties filed expert reports, supporting medical literature, and pre-hearing briefs, the special master held an entitlement hearing at the beginning of March 2020. (ECF 92 at 2-3.) Both parties presented expert witnesses to testify at the hearing. (*Id.* at 14-15.) The petitioner offered Frederick W. Fraunfelder, M.D., as an expert in ophthalmology without objection, and the respondent offered Hamid Bassiri, M.D.-Ph.D., as an expert in immunology and infectious disease without objection. (*Id.*) The special master recognized each doctor as an expert in his respective field. (*Id.*)

Following the entitlement hearing and post-hearing briefing, the special master issued her entitlement decision in February 2022.

The special master first considered whether the petitioner had shown that she suffered from the injuries alleged: PUK, uveitis, and herpes keratitis. (*Id.* at 33-34.) Although the special master found that the petitioner had not shown by preponderant evidence that she suffered from PUK, the special master found that the petitioner had carried her burden to prove by preponderant evidence that she suffered from uveitis and herpes keratitis. (*Id.*)

The special master then considered whether the November 2012 flu vaccine caused those conditions. Because the petitioner did not assert a claim involving an injury on the Vaccine Injury Table, *see* 42 C.F.R. § 100.3, the special master applied the legal test applicable to Non-Table injuries. To prove causation in a Non-Table case, a petitioner must satisfy by preponderant evidence three elements: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the

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[14] Erythema is "abnormal redness of the skin or mucous membranes due to capillary congestion (as in inflammation)." Merriam-Webster, *Medical Definition of* erythema, https://www.merriam-webster.com/dictionary/erythema#medicalDictionary (last visited May 9, 2022).

reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

The special master concluded that the petitioner had failed to establish causation of her uveitis and herpes keratitis from the vaccine under the *Althen* prongs. (ECF 92 at 47.) Regarding the petitioner's uveitis, the special master found that the petitioner failed to meet her burden under all three prongs. The special master found, however, that the petitioner had "met her burden under *Althen* prong one with respect to the flu vaccine's role in the development of [Herpes Simplex Virus ("HSV")] reactivation and subsequent herpes keratitis via the notion of a positive rechallenge." (*Id.* at 39.) Despite concluding that the petitioner had met her burden under prong one of *Althen*, the special master found that the petitioner failed to meet her burden regarding herpes keratitis on the remaining two prongs. (*Id.* at 45, 47.)

Accordingly, the special master denied entitlement upon her finding that the petitioner failed to establish by preponderant evidence that the November 2012 flu vaccine was the cause of her uveitis and herpes keratitis. (ECF 92.)

C. Motion for Review

The petitioner has moved for the Court to review the special master's decision denying compensation. (ECF 94; *see also* ECF 94-2 (Memorandum in Support of the Mot. for Review).) Although the special master found that the petitioner had established that she suffered from both uveitis and herpes keratitis, the petitioner's motion challenges only the special master's analysis regarding herpes keratitis. (ECF 94-2 at 10 n.7.)

The petitioner has raised four objections to the special master's decision:

1. "It was an abuse of discretion for the special master to limit petitioner's evidence with regard to *Althen* prong 1" (*id.* at 12 (bold and capitalization omitted));
2. "The special master's decision to disregard the notations from petitioner's treating physicians was arbitrary, capricious, and not in accordance with law" (*id.* at 13 (bold and capitalization omitted));
3. "The special master required evidence of positive rechallenge in order to meet *Althen* prong two, which is an abuse of discretion, an elevation of petitioner's burden, and not in accordance with the law" (*id.* at 16 (bold and capitalization omitted));
4. "The special master's failure to analyze *Althen* prong 3 as it pertains to the mechanism accepted for *Althen* prong 1

constitutes an abuse of discretion and is not in accordance with law" (*id.* at 21 (bold and capitalization omitted)).

The respondent has opposed the petitioner's motion. (ECF 98.) The Court heard oral argument on April 26, 2022.

II. JURISDICTION AND STANDARD OF REVIEW

The Court of Federal Claims has jurisdiction to review the decisions of special masters under the Vaccine Program. 42 U.S.C. § 300aa-12(e); *see generally* Rules of the Court of Federal Claims ("RCFC") App. B, Title V (providing the rules governing this court's review of a special master's decision). Pursuant to this jurisdiction, the court may "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. § 300aa-12(e)(2)(B); *see also* RCFC App. B, Rule 27.

The Federal Circuit has described the standard of review as "the most deferential possible." *Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992). This court "owes the[ ] findings and conclusions by the special master great deference—no change may be made absent first a determination that the special master was 'arbitrary and capricious.'" *Id.* The degree of deference depends on which aspect of the special master's judgment is under review. *Id.* at 870 n.10. This court "may set aside the decision of a special master only if the special master's fact findings are arbitrary and capricious, its legal conclusions are not in accordance with law, or its discretionary rulings are an abuse of discretion." *Turner v. Sec'y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001).

III. DISCUSSION

The special master denied compensation because the petitioner failed to establish by preponderant evidence the three *Althen* prongs—the test for establishing causation in a vaccine case involving a Non-Table injury. The petitioner argues that the special master's ruling was arbitrary, capricious, an abuse of discretion, and not in accordance with the law. The petitioner objects to the special master's analysis under each *Althen* prong.

A. *Althen* Prong 1

In her first objection, the petitioner argues that it was an abuse of discretion for the special master to limit the petitioner's evidence regarding the first *Althen* prong. (ECF 94-2 at 12-13.) Under the first *Althen* prong, a petitioner must "show by preponderant evidence that the vaccination brought about her injury by providing . . . a medical theory causally connecting the vaccination and the injury . . . ." *Althen*, 418 F.3d at 1278.

The petitioner claims that the special master committed reversible error when she forbade Dr. Fraunfelder from testifying about molecular mimicry as a causal theory for the petitioner's injury, thus limiting his testimony to hypersensitivity. (ECF 94-2 at 12.)

When asked about the causal mechanisms for vaccine-induced uveitis, Dr. Fraunfelder provided the following response:

> I think the thinking most recently for uveitis specialists and people in my profession is that *it's more likely than not that a delayed-type hypersensitivity reaction*, Type 4 cell-mediated immunity reaction which occurs days after the offending agent for vaccines, but *we've explored other possibilities and ruled out other possibilities. And I know Your Honor's probably familiar with these, but there is molecular mimicry*. There's [*sic*] possible agonists in vaccines.

(ECF 87, Tr. of Entitlement Hr'g at 33:22–34:6 (emphasis added).)[15]

Before Dr. Fraunfelder discussed molecular mimicry further, the special master interrupted:

> I'm just going to do something I rarely do which is interrupt, because if your standard is more likely than not and he just said it's more likely than not, then implicit in that is it's not more likely than not that it's molecular mimicry because in order for it to be more likely than not, it cannot be more likely than not something else. So if you're saying it's more likely than not that it's hypersensitivity, we can go with that.

(*Id.* at 34:7-15.) Dr. Fraunfelder replied, "Okay." (*Id.* at 34:16.) The special master then told the petitioner's counsel that he could not "have it both ways"; she told him to "pick a pony." (*Id.* at 34:17-22.)

Following the special master's comments, the petitioner's counsel clarified that "the primary mechanism that [Dr. Fraunfelder] opined in this case was delayed-type . . . hypersensitivity reaction . . . ." (*Id.* at 35:3-5.) Dr. Fraunfelder confirmed that counsel's description of his opinion was correct. (*Id.* at 35:6.)

In her entitlement decision, the special master characterized Dr. Fraunfelder's testimony as abandoning his theory of molecular mimicry. (ECF 92 at 20.) As a result, the special master did not analyze the petitioner's theory of molecular mimicry under the *Althen* prongs.

Although the special master limited Dr. Fraunfelder's testimony, she found in favor of the petitioner on the first *Althen* prong. The special master concluded that the petitioner "met her

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[15] As noted earlier, the petitioner has focused her objections only on the special master's analysis regarding herpes keratitis. Although the exchange from the entitlement hearing discussed in this section pertained to uveitis, the testimony also appears relevant to herpes keratitis. (*See* ECF 87, Tr. of Entitlement Hr'g at 38:18–40:2 (discussing herpes keratitis as part of the chain of events of Dr. Fraunfelder's hypersensitivity theory).)

burden under *Althen* prong one with respect to the flu vaccine's role in the development of HSV reactivation and subsequent herpes keratitis via the notion of a positive rechallenge." (ECF 92 at 39.) The petitioner does not object to the special master's conclusion that the HSV-reactivation theory satisfied the first *Althen* prong, but implicit in the petitioner's objection is that the special master's failure to consider molecular mimicry as an alternative mechanism tainted the special master's decision under the other two *Althen* prongs.[16]

The special master did not abuse her discretion. In pointing out that two theories could not separately be more likely than not the cause, the special master merely limited Dr. Fraunfelder's testimony to the theory that he had opined was "more likely than not" the cause of the petitioner's uveitis. (ECF 87, Tr. of Entitlement Hr'g at 34:7-15.) Of the three expert reports written by Dr. Fraunfelder, only the third mentions molecular mimicry as a possible additional mechanism of causation, noting that "[s]everal peptides have been shown to induce uveitis via [molecular mimicry] . . . ." (ECF 49-1, Pet'r's Ex. 33 at 1 (citation omitted).) Aside from this single sentence, Dr. Fraunfelder provided no further explanation in his reports of how molecular mimicry is relevant to this case. Indeed, he testified that, in his opinion, a delayed-type hypersensitivity reaction was the primary causal mechanism for the petitioner's injury, and that other possibilities had been explored and ruled out. (ECF 87, Tr. of Entitlement Hr'g at 34:2-3, 35:3-6.) Because the petitioner's expert himself had downplayed the likelihood that molecular mimicry was the cause of the petitioner's injury, it was not error to foreclose further testimony on that topic.

The special master's analysis finding that the petitioner had met her burden on the first prong of *Althen* but foreclosing reliance on the theory of molecular mimicry was supported by the record and was not an abuse of discretion.

B. *Althen* Prong 2

The petitioner's second and third objections pertain to the second *Althen* prong. Under the second *Althen* prong, a petitioner must provide "a logical sequence of cause and effect showing that the vaccination was the reason for the injury . . . ." *Althen*, 418 F.3d at 1278. This showing "must be supported by a sound and reliable medical or scientific explanation." *Knudsen by Knudsen v. Sec'y of Dep't of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994).

[16] The respondent argues that, if the Court found error in the limitation of Dr. Fraunfelder's testimony, that error would be harmless because the special master found in favor of the petitioner on the first *Althen* prong. (ECF 98 at 13 n.7.) Although the petitioner's claim of error has been rejected, had it been accepted, that error would not have been harmless; the special master's conclusions under the first prong of *Althen* necessarily affect the analysis under the other *Althen* prongs.

1. Notations of the Treating Physicians

As her second objection, the petitioner asserts that the special master failed to explain why she disregarded the treating physicians' opinions in her second-prong analysis. (ECF 94-2 at 15.) The petitioner argues that that alleged failure was arbitrary and capricious and an abuse of discretion. (*Id.* at 15-16.)

Special masters must consider the opinions of treating physicians. *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). The medical opinions of treating physicians on causation are "quite probative." *Id.* "[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* (quoting *Althen*, 418 F.3d at 1280) (second modification in original). A treating physician's recommendation to withhold a vaccination can be probative evidence of causation. *Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Hum. Servs.*, 569 F.3d 1367, 1377 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1326). The special master must consider the medical evidence in the entire record—including the treating physician's opinions—but "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1).

The petitioner asserts that there are "multiple and robust notations from [the] petitioner's treating physicians implicating her November 3, 2012 flu vaccine as a cause of her injury." (ECF 94-2 at 13.) As examples, she highlights five notations:

- "On November 6, 2014, Dr. Karen Smith noted, 'In reviewing her records she noted the eye inflammatory disease came on immediately after the flu shot. **It is immunologically possible that this could be the trigger.**'" (*Id.* (emphasis in original) (citation omitted).)
- "On April 23, 2015, Dr. Michael Foote, [the petitioner's] ophthalmologist, remarked, 'The entire episode began [right eye] 3 days subsequent to flu vaccination shot.'" (*Id.* (citation omitted).)
- "On April 18, 2016, Dr. Lookman Lawal noted, 'Allergies[:]. . . .**FLU SHOT REACTION EYE INFLAMMATORY. . . .She had an autoimmune reaction in her right eye after a flu shot [times] 2 years ago.**'" (*Id.* (internal modifications, formatting, and emphasis in original) (citation omitted).)
- "On November 4, 2016, Dr. Smith indicated, '[the petitioner] . . .was given a skin test for TB. . . . She has an enormous [reaction] and since then her eyes are flaring. . . . **Note to avoid all things that stimulate dendritic cells which is vaccines and BCG as it activates her eye disease**[.]'" (*Id.* (first modification

added) (all other internal modifications, formatting, and emphasis in original) (citation omitted).)

- "On December 19, 2017, Dr. Atle Einer [*sic*] Østern, an ophthalmologist at Oslo University Hospital, noted that, '**Patient seems to react strongly to vaccines, also around the eyes. This is assumed to secondarily set off Herpes Keratitis.**'" (*Id.* (emphasis in original) (citation omitted).)

The special master's decision did not disregard the treating physicians' notations. The special master's opinion extensively catalogs the petitioner's medical history, including the notations of the petitioner's treating physicians. (ECF 92 at 4-12.) The special master explained that she "considered the notations from Petitioner's treaters ascribing causation to the flu vaccine" and weighed those records "against Petitioner's treaters that considered both her flu vaccine and HSV status, and alternatively ascribed causation to the latter." (*Id.* at 42.) The special master also noted that the relevant notations regarding causation were made more than two years after the flu vaccine at issue, and the special master found that the petitioner failed to present preponderant evidence that those notations referred to the same flu vaccine. (*Id.*) Although this latter finding by the special master is highly questionable, it does not undermine her otherwise reasonable analysis.

The entitlement decision evidences a thorough review of the record as a whole and reflects that the special master considered the notes of the treating physicians. The special master ultimately afforded the treating physicians' notations ascribing causation to the flu vaccine less weight than other evidence, and that decision was reasonable. (*See id.*) Most of the notes of the petitioner's treating physicians are best read not as conclusions on the cause of the petitioner's injury but as reportage of the petitioner's medical history. They are highly probative but not dispositive of the question of causation. The special master was entitled to find other evidence more probative, if she considered and evaluated all the evidence, and her opinion reflects that she did. To afford talismanic or dispositive weight to the notes of treating physicians, as the petitioner urges, would be to eviscerate the role of the special master.

Although the petitioner characterizes her objection regarding the weight given to the notes of the treating physicians as a legal question, she is really asking the Court to reweigh the evidence, and that task is beyond the Court's authority. *See Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) ("We do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder."). Accordingly, the Court rejects the petitioner's second objection.

2. Positive Rechallenge

As her third objection, the petitioner argues that the special master improperly required evidence of a positive rechallenge to meet the second *Althen* prong. (ECF 94-2 at 16-20.) As Dr. Fraunfelder testified, "any time there is a rechallenge of a drug, like a vaccine being

administered a second time and then that person gets a reaction again like they did the first time, that's called a positive rechallenge." (ECF 87, Tr. of Entitlement Hr'g at 25:15-19.)

The Federal Circuit has held that "petitioners need not present 'epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.'" *Lozano v. Sec'y of Health & Hum. Servs.*, 958 F.3d 1363, 1370 (Fed. Cir. 2020) (quoting *Capizzano*, 440 F.3d at 1325). "[M]edical records and medical opinion testimony can satisfy *Althen* prong two, and . . . evidence used to satisfy one of the *Althen* prongs can overlap to satisfy another prong." *Id.* (citing *Capizzano*, 440 F.3d at 1326). The petitioner argues that the special master abused her discretion and acted contrary to law by requiring evidence of positive rechallenge. (ECF 94-2 at 16.) The petitioner argues that the special master misapprehended the petitioner's submitted medical literature under the first-prong analysis. This alleged error led the special master improperly to require certain affirmative evidence under the second-prong analysis.

The causal theory accepted under the first prong determines which theory of causation the special master must consider under the second prong. The Court first addresses the causal theory accepted by the special master under her first-prong analysis and then analyzes the special master's evaluation of the evidence to support the second prong under that causal theory. Finally, the Court considers whether the special master imposed on the petitioner an improperly high burden of proof.

i. Causal Theory in *Althen* Prong 1

The petitioner's third objection is grounded on what the petitioner calls a mislabeling of the causal mechanism under the first *Althen* prong. (ECF 94-2 at 16.) The special master concluded under her analysis of the first *Althen* prong that the petitioner had "met her burden . . . with respect to the flu vaccine's role in the development of HSV reactivation and subsequent herpes keratitis *via the notion of a positive rechallenge*." (ECF 92 at 39 (emphasis added).) The petitioner argues that "nothing about the mechanism of flu vaccination reactivating latent HSV requires proof of positive rechallenge"; instead, she argues that "[p]ositive rechallenge provides strong proof of concept for causality but is not itself a mechanism." (ECF 94-2 at 16.)

The petitioner built her case primarily on Dr. Fraunfelder's causal theory of Type IV hypersensitivity. (*See* ECF 24-1 (Pet'r's Ex. 19, Expert Report of Dr. Fraunfelder), 37-1 (Pet'r's Ex. 32, Suppl. Expert Report of Dr. Fraunfelder), 49-1 (Pet'r's Ex. 33, Second Suppl. Expert Report of Dr. Fraunfelder).) Dr. Fraunfelder himself referred to the causal chain as "a domino effect that started with the vaccination . . . ." (ECF 24-1 at 2.) He opined that the petitioner's injuries progressed on the following chain of events:

> Briefly, the flu vaccination in Ms. Quintana's case led to the development of uveitis caused by a Type IV hypersensitivity reaction. The altered immune status caused by her uveitis led to the activation of an opportunistic shingles infection, which led to zoster

> (shingles) keratitis. The zoster keratitis led to neurotrophic keratitis, which led to a permanent corneal scar.

(ECF 37-1 at 1.) In short, as summarized by the special master, the "[p]etitioner argue[d] that the flu vaccine causes an altered immune system via a Type IV hypersensitivity reaction, which creates a susceptibility to HSV, and herpes keratitis can develop." (ECF 92 at 39.)

Dr. Bassiri, the respondent's expert, put forward HSV reactivation as an alternative causal theory of the petitioner's uveitis. (*See* ECF 27-1 (Resp't's Ex. A, Expert Report of Dr. Bassiri), 45-1 (Resp't's Ex. M, Suppl. Expert Report of Dr. Bassiri), 52-1 (Resp't's Ex. N, Second Suppl. Expert Report of Dr. Bassiri).) He opined that Dr. Fraunfelder had the order of injuries flipped because HSV reactivation is a known cause of uveitis:

> Importantly, HSV is an extremely common human virus (almost 90% percent [*sic*] of adults worldwide carry this virus) and its reactivation is known to cause uveitis and neurotrophic keratitis. Moreover, primary HSV disease and HSV reactivation initially present in a large percentage of patients as a cold with fever (reviewed in my last report [ECF 27-1]), which Ms. Quintana appeared to have prior to her visit to her optometrist . . . . Given the fact that this virus is essentially endemic and its reactivation is quite common, and Ms. Quintana's presentation appears to match the clinical features of this disease, I am not sure why one would invoke an unproven association as being the cause of the uveitis [(referring to Dr. Fraunfelder's proposed causal link between vaccinations and uveitis)].

(ECF 45-1 at 2.)

Under the first *Althen* prong, the special master found that the petitioner had not presented "preponderant evidence that a Type IV hypersensitivity reaction can lead to herpes keratitis." (ECF 92 at 39.) Despite failing to prove her primary causal theory by preponderant evidence, the petitioner has not objected to that finding.

The special master based her findings under the first prong of *Althen* on evidence that the petitioner put into the record. The special master acknowledged that the "[p]etitioner does not explicitly argue that the flu vaccine triggers HSV reactivation via a positive rechallenge, [but] the record as a whole, including Petitioner's submitted medical literature and testimony from both experts, provides evidence that the flu vaccine can cause HSV reactivation and eventual herpes keratitis via a positive rechallenge." (ECF 92 at 39.)

At the entitlement hearing, the petitioner's counsel specifically asked both expert witnesses whether a vaccine could reactivate a latent HSV infection. (ECF 87, Tr. of Entitlement Hr'g at 44:8-9, 110:18-20.) In response, both experts testified that it was possible. (*Id.* at 44:10, 110:21-25–111:1-3.) Moreover, the petitioner submitted an article titled, "Immunologic factors may play a role in herpes simplex virus 1 reactivation in the brain and retina after influenza

vaccination," written by Lynn M. Hassman and others ("the Hassman article"). (ECF 79-1, Pet'r's Ex. 44.) The Hassman article, the special master found, supported the experts' agreement that a vaccine could reactivate a latent HSV infection. (ECF 92 at 40.) As the special master explained, the authors determined that disruptions in the immune system, such as vaccines, could activate the virus, and the authors noted a study reporting rare (13 out of 38 million doses over 10 years) cases of neurologic complications after influenza vaccinations. (*Id.* (citing ECF 79-1, Pet'r's Ex. 44).) The special master found that the rarity of the occurrence did not prevent the petitioner from meeting her burden under the first *Althen* prong. (*Id.* at 41.)

The special master had reason to focus on the notion of positive rechallenge. When Dr. Fraunfelder was asked about the significance of the Hassman article, he emphasized the significance of positive rechallenge:

> This article is significant in that the flu vaccine created severe -- severe inflammation in the central nervous system. And the brain is considered a neurologic tissue in the area of the retina because the retina is contiguous with the nerves of the optic nerve and then the rest of the brain. So this person got retinitis, and they got it each time that they had the vaccine. So this is positive rechallenge twice. And that's really strong evidence for the flu vaccine causing [central nervous system] side effects including retinitis which is a type of inflammation like uveitis.

(ECF 87, Tr. of Entitlement Hr'g at 45:11-21.)

Based, as it is, on the petitioner's own evidence and testimony adduced by the petitioner's counsel, the special master's analysis and conclusion under the first prong of *Althen* were "hardly out of left field," and the petitioner has not raised an objection based on unfair surprise. *See Sword v. United States*, 44 Fed. Cl. 183, 190 (1999) (finding no unfair surprise when the objecting party had opportunity to express opinions on the matter at issue). Judge Schwartz recently remanded a case to a special master because, in part, the special master issued a decision based on a theory of injury and a theory of causation that the petitioner had not advanced in her expert reports or briefing. *Doles v. Sec'y of Health & Hum. Servs.*, No. 17-642V, 2022 WL 1231434, at *3-4 (Fed. Cl. Apr. 1, 2022). Like the petitioner in *Doles*, the petitioner here did not advance in her expert reports or briefs the causal theory ultimately accepted by the special master under the first *Althen* prong. The petitioner did, however, advance the possible link between the vaccine and HSV reactivation during questioning at the entitlement hearing, and Dr. Fraunfelder highlighted the notion of positive rechallenge when explaining the supporting medical literature.

The petitioner had three rounds of expert reports, an entitlement hearing with an expert witness, and post-hearing briefing. The expert testimony of both experts and the submitted literature were sufficient evidence in the record to establish a link between the vaccine and HSV reactivation, as found by the special master. The petitioner, however, did not pursue that causal theory in post-hearing briefing. (*See* ECF 88.) The petitioner instead remained committed to Dr. Fraunfelder's domino theory, which started with uveitis being caused by a Type IV

hypersensitivity reaction to the vaccine. (*Id.* at 20-23.) As a result, the special master had little evidence in the record to analyze the second and third *Althen* prongs under the theory of HSV reactivation.

ii. Evidence Under Second Prong

After the special master rejected Dr. Fraunfelder's domino theory on the first *Althen* prong, the petitioner could prevail under the second *Althen* prong only under the HSV-reactivation theory, the causal theory accepted by the special master. The only evidence that the special master had on that theory was the Hassman article, which described reactivation in a single patient. (ECF 79-1, Pet'r's Ex. 44.) The patient from the Hassman article was distinguished from the petitioner by Dr. Bassiri during his testimony. (ECF 87, Tr. of Entitlement Hr'g at 78:20–80:9.) He pointed out two differences: the first was "that the authors noted themselves . . . that they had suspicion that [the patient had] an immune defect or immune dysregulation," and the second was that the Hassman patient had had repeated reactions to vaccinations. (*Id.* at 79:12–80:9.)

The two differences raised by Dr. Bassiri form the basis of the petitioner's objection on review to the special master's analysis of the second prong of *Althen*. The petitioner argues that, in contravention of Federal Circuit precedents, the special master required evidence of a positive rechallenge and of an immune defect. *See Lozano*, 958 F.3d at 1370 ("[P]etitioners need not present 'epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.'" (quoting *Capizzano*, 440 F.3d at 1325)).

The petitioner mischaracterizes the special master's analysis as requiring evidence of a positive rechallenge and of an immune defect when the special master noted the lack of evidence in the record to support a theory of HSV reactivation. Noting the absence of evidence, however, is not the same as requiring evidence.

The special master correctly noted that the "[p]etitioner's record does not show that she had negative reactions to prior flu vaccines." (ECF 92 at 46.) As a result, the special master concluded that the petitioner could not "establish that her November 3, 2012, flu vaccine caused her HSV and herpes keratitis via a positive rechallenge." (*Id.*) The Hassman article, the petitioner's only proof of causation under the HSV-reactivation theory, was therefore distinguishable, and its support for the petitioner's case was diminished. A petitioner must present some evidence to support a causal theory, even if that evidence, on its own, is not required to prove the theory. The petitioner was left with no evidence in the record of any kind that could support the argument that a theory of HSV reactivation, the only causal theory the special master had found to satisfy prong one of *Althen*, satisfied prong two of *Althen*.

The petitioner also argues that "[t]he Special Master . . . required [the] petitioner to provide direct evidence of an 'immune defect' in order to prevail on *Althen* prong 2." (ECF 94-2 at 18 (citing ECF 92 at 44).) The special master, however, again simply noted the absence of any evidence to support the only causal theory that met prong one of *Althen*. The Hassman article notes that "[a] subtle immunologic deficiency in our patient may have lowered the

threshold for clinically significant HSV reactivation in the [central nervous system]." (ECF 79-1, Pet'r's Ex. 44 at 4.) The special master found Dr. Bassiri's opinion persuasive in distinguishing the Hassman patient from the petitioner. (ECF 92 at 44.) To distinguish the Hassman patient, Dr. Bassiri noted "that the record does not contain evidence that [the petitioner] had a pre-existing immune defect . . . ." (*Id.* (citing ECF 87, Tr. of Entitlement Hr'g at 79:18-20, 80:7-9).)

While considering what evidence was not in the record, the special master also specifically considered the evidence that was in the record of the petitioner's family history and genetic susceptibility for developing autoimmune diseases:

> Respondent's expert addressed Petitioner's family history and genetic susceptibility for developing autoimmune diseases, such as uveitis, following viral infections like herpesviruses. He explained that the fact that Petitioner has a sister "with possible rheumatoid arthritis" and a son with "possible ankylosing spondylitis" suggests "a relatively strong predisposition to autoimmune diseases." Resp't's Ex. A at 5 [ECF 27-1]. He also testified that a positive HLA-B27 haplotype, present in Petitioner, may result in a predisposition to a variety of autoimmune phenomenon, including uveitis. Tr. 85:1–3 [ECF 87]. While Respondent noted potential genetic susceptibilities and predispositions to autoimmune diseases, the record fails to provide preponderant evidence that Petitioner, in fact, suffers from an immune *defect*.

(*Id.* at 44 n.85 (emphasis in original).) As is apparent from the excerpt, in concluding that there was a lack of preponderant evidence on this issue, the special master found Dr. Bassiri's explanation of the evidence more persuasive than the petitioner's explanation of the evidence.

Relying on the testimony of Dr. Bassiri and the evidence in the record, the special master found that the "[r]espondent ha[d] successfully negated [the Hassman article's] effectiveness as it relates to Petitioner's case under *Althen* prong two." (ECF 92 at 44.) The special master did not apply an improper requirement; she distinguished the petitioner's circumstances from those described in the Hassman article. The petitioner failed to demonstrate otherwise.

iii. The Petitioner's Burden of Proof

The petitioner must present some evidence to meet her preponderance-of-evidence burden under the *Althen* test. Aside from the Hassman article, which the special master found sufficiently distinct, the petitioner's support for the second prong was sparse. At oral argument before the Court on review, the petitioner's counsel listed three sources of evidence that should have established the second *Althen* prong: (1) the notations of the treating physicians; (2) the lack of an alternative theory of causation; and (3) the temporal relationship between the vaccine and the petitioner's injuries (more on this last point to follow). (ECF 100, Tr. of Oral Arg. at 25:3-10.)

These sources of evidence do not undercut the special master's analysis. First, as discussed, *supra* III.B.1, the special master considered and discounted the weight of the treating physicians' notations given the other evidence presented, and the Court may not reweigh that evidence. Second, on the burden-shifting standard of causation, an alternative theory is required by the respondent only to rebut a claim after a petitioner has established the three *Althen* prongs. *Althen*, 418 F.3d at 1278. Otherwise, the burden is not on the respondent to offer alternative causes for an alleged injury. The burden remains on the petitioner until the three *Althen* prongs are met. *Id.* Finally, even if the temporal relationship had been considered under the second-prong analysis, that evidence would stand alone. *See Capizzano*, 440 F.3d at 1326 (holding that evidence used to satisfy one *Althen* prong may overlap to satisfy another prong). A temporal association alone does not prove causation. *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1323 (Fed. Cir. 2010).

The petitioner's motion implies that the special master penalized the petitioner for not testifying. (*See* ECF 94-2 at 17-18 (arguing that "the Special Master found fatal that [the] petitioner did not exercise her right to testify").) The special master looked for other support in the record and noted that the petitioner would have benefited from testifying. (ECF 92 at 44 n.83.) The special master did not penalize the petitioner for not testifying. Dr. Fraunfelder testified that evidence of a positive rechallenge is strong evidence of a causal relationship between a drug and a side effect. (ECF 87, Tr. of Entitlement Hr'g at 25:23–26:2.) Thus, the special master found it relevant whether the petitioner had ever had an adverse reaction to prior flu vaccines. (*See* ECF 92 at 44.) Because the petitioner had not offered information on previous adverse flu-vaccine reactions, the special master had no petitioner-specific evidence of a positive rechallenge under the second-prong analysis.[17] The special master did not err in noting that absence of evidence.

The special master's second-prong analysis is grounded in the record and shows a consideration of the petitioner's arguments and submissions. The special master credited Dr. Bassiri's testimony, which distinguished the patient in the Hassman study from the petitioner. In doing so, the special master surveyed the evidence that the petitioner had and had not offered. Because the petitioner had not explicitly proposed HSV reactivation as a causal theory, it is not clear that the special master needed to address that theory at all. The special master appears to have searched the record for anything that could plausibly support the petitioner's entitlement to compensation, even though the HSV reactivation theory was not specifically argued by the

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[17] Although the special master did not reference the petitioner's adverse reaction to a tuberculosis test in the discussion of a positive rechallenge, the special master did not ignore this evidence, as the petitioner argues. (*See* ECF 94-2 at 20.) Earlier in her decision, the special master specifically cited the medical record noting the adverse tuberculosis test. (ECF 92 at 42 n.81.) She concluded that "[s]uch notations do not provide preponderant support for Petitioner's claim that her November 3, 2012, flu vaccine caused her uveitis and related injuries." (*Id.*) It is sufficient that the special master considered the evidence and found it wanting. The petitioner disagrees with the special master's assessment, but having considered the evidence on the point, the special master's rejection of the claim is not arbitrary and capricious.

petitioner. The special master's opinion reflects a thorough survey of the evidence in the record and searching scrutiny of that evidence; but it does not reflect that the special master converted missing evidence into evidence that was required to support a finding of entitlement. The petitioner has not shown that the special master erred under the second prong.[18]

C. *Althen* Prong 3

In her fourth objection, the petitioner argues that the special master failed to analyze the third *Althen* prong as it pertains to HSV reactivation, the only causal theory accepted by the special master under the first *Althen* prong. (ECF 94-2 at 21.) Under the third *Althen* prong, a petitioner must show "a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

The special master found that the petitioner had not met her burden under the third *Althen* prong with respect to the theory of positive rechallenge:

> It is also compelling that neither expert discussed the onset time of a positive rechallenge. While the authors of the Hassman et al. article found that the patient in the study experienced HSV flares "within days" of his yearly flu vaccines, without more, I am unable to find by a preponderant standard that Petitioner experienced the onset of her HSV symptoms consistent with the timeframe for a positive rechallenge to occur.

(ECF 92 at 47 (footnote omitted).) That reference to the patient in the Hassman article is the only reference to HSV reactivation in the special master's third-prong analysis.

The petitioner again argues that positive rechallenge is not required for HSV reactivation, and that there is enough evidence in the record to establish the temporal relationship described in the Hassman article. (ECF 94-2 at 21-22.) For those reasons, the petitioner argues that the special master's analysis is insufficient. (*Id.*)

The special master did not err in her third-prong analysis. Because the special master's conclusions under the second-prong analysis have been upheld, there is no basis to reject the third-prong analysis. The petitioner failed to establish the second prong, so the special master had no obligation to reach the third prong at all. *See W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1358 (Fed. Cir. 2013) (holding that a special master did not need to evaluate each *Althen* prong after failing one prong). Nonetheless, the special master here did consider the expert testimony and the relevant medical literature in the record pertaining to the third *Althen* prong. The special master acknowledged the temporal relationship described in the Hassman

[18] Although the special master rejected a causal theory of hypersensitivity under the first *Althen* prong, the special master nonetheless analyzed the theory under the second prong. (ECF 92 at 45.) She found that, as for the HSV-reactivation theory, the petitioner had not established a logical cause and effect for the hypersensitivity theory. (*Id.*)

article and determined that the Hassman article, without more, was insufficient for the petitioner to meet the preponderant standard under the third prong. The Court does not disturb that factual finding.

IV. CONCLUSION

Although the petitioner's assignments of error are couched largely as legal issues, the petitioner primarily objects to the special master's assessment of the evidence. Under the Vaccine Program, a reviewing court may not reassess the evidence under a motion for review. The entitlement decision reveals a thorough review of the entire record, and the petitioner has not shown that the special master improperly applied the *Althen* prongs. In applying the *Althen* prongs, the special master considered the evidence presented to her and concluded that the petitioner had not met her burden. The special master's entitlement decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.

The petitioner's motion for review (ECF 94) is **DENIED**. The special master's entitlement decision denying compensation to the petitioner (ECF 92) is **AFFIRMED**.

The Clerk is **DIRECTED** to enter judgment accordingly.

The parties shall review this decision and notify the Court no later than **June 1, 2022**, of any proposed redactions to the opinion so that the Court may issue it publicly.

s/ Richard A. Hertling
Richard A. Hertling
Judge